



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,639	09/18/2003	Timothy Vickers	ISIS0001-100/CORE0027US	4524
34138	7590	06/02/2006	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			ZARA, JANE J	
			ART UNIT	PAPER NUMBER

1635

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/664,639	Applicant(s) VICKERS ET AL.	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 18-26, 29-34, 50, 51, 56-60, 63, 69-75, 77 and 79-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9, 18-26, 29-34, 50, 51, 56-60, 63, 69-75, 77, 79-107 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communication filed 5-25-06.

Claims 1-9, 18-26, 29-34, 50, 51, 56-60, 63, 69-75, 77, 79-107 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 4, 6-9, 18-26, 29-34, drawn to methods of identifying a multifunctional oligomeric compound to modulate expression of RNA wherein the target region is identified by a single stranded oligomeric gene walk, classifiable in class 435, subclass 6.
- II. Claims 1, 3, 5-9, 18-26 and 29-34, drawn to methods of identifying a multifunctional oligomeric compound to modulate expression of RNA wherein the target region is identified by secondary structure analysis, classifiable in class 435, subclass 6.
- III. Claim 2, drawn to a multifunctional oligomeric compound, classifiable in class 536, subclass 23.1.
- IV. Claim 50, drawn to a method of selecting a single stranded oligomeric compound comprising contacting a target RNA with one or more double stranded oligomeric compounds, classifiable in class 435, subclass 6.

Art Unit: 1635

- V. Claim 51, drawn to a method of selecting a double stranded oligomeric compound comprising contacting a target RNA with one or more single stranded oligomeric compounds, classifiable in class 435, subclass 6.
 - VI. Claims 56-60, 63, 69-75, 77 and 79-84, drawn to SiRNA oligomeric compounds, classifiable in class 536, subclass 24.5.
 - VII. Claims 85-99, drawn to methods of eliciting cleavage of a target mRNA in a cell, classifiable in class 435, subclass 91.31.
 - VIII. Claims 100-107, drawn to antisense oligomeric compounds, classifiable in class 536, subclass 24.5.
- Applicants are additionally required to elect a single target gene and target region, each comprising a distinct and different invention (see e.g., claim 9 for the various target regions).

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, IV, V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise methods that are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I, II, VI, V and VII comprise steps which are not required for or present in the methods of the other groups: single stranded

Art Unit: 1635

oligomeric gene walk (Group I); secondary structure analysis (Group II); selecting a single stranded oligomeric compound (Group IV); selecting a double stranded oligomeric compound (Group V); eliciting cleavage of a target mRNA in a cell (Group VII). The operation, function and effects of these different methods are distinct from each other. Therefore, the inventions of these different and distinct groups are capable of supporting separate patents.

Inventions III, VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise compositions that are biologically, chemically, structurally and functionally different and distinct from each other and thus one does not render the other obvious. The multifunctional oligomeric compound of Group III, the SiRNA oligomeric compounds of Group VI, the antisense oligomeric compounds of Group VIII and the various target genes and/or regions claimed are not required to make each other. Therefore, the inventions of these different Groups are capable of supporting separate patents.

Inventions I, II, IV, V and VII are unrelated to inventions III, VI and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together or if they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise methods that are biologically and functionally different and distinct from each other and do not require the compounds comprising the multifunctional oligomeric

Art Unit: 1635

compound of Group III, the SiRNA oligomeric compounds of Group VI or the antisense oligomeric compounds of Group VIII, nor the different target regions and/or target genes claimed. Thus one does not render the other obvious. The methods of Groups I, II, VI, V and VII comprise different and distinct steps from each other and do not require the compounds of the different and distinct Groups. The operation, function and effects of these different methods are distinct from each other. Therefore, the inventions of these different and distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices

Art Unit: 1635

published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
5-30-06


JANE ZARA, PH.D.
PRIMARY EXAMINER